UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

INFORMED CONSENT ACTION NETWORK, Plaintiff, -against- CENTERS FOR DISEASE CONTROL AND PREVENTION AND HEALTH AND HUMAN SERVICES, Defendant.	Civil Action No. 1:22-cv-481

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, as for its Complaint regarding a Freedom of Information Act request against the above-captioned Defendant, alleges as follows:

INTRODUCTION

1. Between December 2020 and February 2021, the Food and Drug Administration ("**FDA**") issued Emergency Use Authorizations for three COVID-19 vaccines,[1] one of which subsequently received FDA approval in August 2021 and another on January 31, 2022.[2] While the FDA approved these vaccines, the Centers for Disease Control and Prevention ("**CDC**"), an agency within the Department of Health and Human Services ("**HHS**"), is charged with

[1] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (last visited May 11, 2022); https://http://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (last visited May 11, 2022); https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine (last visited May 11, 2022).

[2] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited May 11, 2022); https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine (last visited May 11, 2022).

monitoring the safety of all vaccines, including the COVID-19 vaccines approved by the FDA. The CDC claims that these "COVID-19 vaccines are being administered under the **most intensive vaccine safety monitoring effort in U.S. history[.]**"[3]

2. The federal government has mandated that millions of Americans receive these vaccine products. HHS has also given pharmaceutical companies complete immunity for injuries caused by those products. Mandating that millions of Americans inject a product for which they cannot hold the manufacturer liable if the product injures them demands complete **transparency**, especially when it comes to releasing the data underlying the product's safety. FOIA exists precisely so that the American people can obtain transparency and, in this case, obtain the data which supports the CDC's claims to intensive safety monitoring.

3. The FDA and CDC have said that their prior primary existing vaccine safety monitoring program was incapable of determining causation and was otherwise unreliable to assess the safety of COVID-19 vaccines, and hence deployed a new safety monitoring system for the COVID-19 vaccines, v-safe.

4. V-safe is a smartphone app that allows vaccine recipients to "tell CDC about any side effects after getting the COVID-19 vaccine."[4] The purpose of the app "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[5]

5. The CDC has explained that the data submitted to v-safe is "collected, managed,

[3] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (last visited May 11, 2022).

[4] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html (last visited May 11, 2022).

[5] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf (last visited May 11, 2022).

and housed on a secure server by Oracle,"[6] a private computer technology company. Although the CDC has "access to the individualized survey data," Oracle has access to "aggregate deidentified data for reporting."[7]

6. Plaintiff asked, through its instant FOIA request, that the CDC produce all data submitted to the v-safe program. To provide transparency regarding the government's claim that COVID-19 vaccines are "safe and effective,"[8] the public should have immediate access to all disclosable v-safe data. Hence, once the CDC produces that data, Plaintiff intends to make it publicly available. Even though disclosable data already exists, and even though the CDC has never objected to its production, the CDC has failed to produce it to Plaintiff and the American public. The federal government is thereby not only failing to live up to its promise of transparency but is also failing to comply with FOIA.

7. Plaintiff Informed Consent Action Network ("**Plaintiff**") is a non-profit organization that advocates for informed consent and transparency, and disseminates information necessary for same with regard to all medical interventions. *See* ICAN's Declaration ("**Exhibit 1**.") It intends to make all v-safe data immediately available to the public so that independent scientists can immediately analyze that data. It believes that we need all hands-on deck, both inside and outside the government, to address serious and ongoing issues with the vaccine program,

[6] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf p. 8 (last visited May 11, 2022).

[7] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf p. 9 (last visited May 11, 2022) (emphasis added).

[8] *See*, *e.g.*, https://www.fda.gov/media/146269/download (materials for February 26, 2021 meeting of the Vaccines and Related Biological Products Advisory Committee ("VRBPAC") stating "[r]eactogenicity profiles of mRNA vaccines in v-safe monitoring are consistent with what was observed in clinical trials") (last visited May 11, 2022); https://www.fda.gov/media/150054/download (materials from June 10, 2021 meeting of VRBPAC stating "[i]nitial safety findings from Pfizer-BioNTech COVID-19 vaccination of 12-15-year-olds from v-safe and VAERS surveillance are consistent with results from pre-authorization clinical trials"); https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (materials from October 21, 2021 meeting of Advisory Committee on Immunization Practices stating "[n]o unexpected patterns of adverse events were identified") (last visited May 11, 2022).

including waning immunity, adverse reactions, etc. Locking out independent scientists from addressing these issues is, at best, irresponsible and unethical.

8. To make public the v-safe data, Plaintiff made a request to the CDC pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). Plaintiff's FOIA request was for "[a]ll data submitted to v-safe since January 1, 2020." The CDC issued an acknowledgment letter regarding ICAN's request but failed to make a final determination regarding the request within FOIA's thirty-day time requirement. Plaintiff brings this action to challenge the CDC and HHS' failure to timely respond to ICAN's FOIA request.

PARTIES

9. Plaintiff is a not-for-profit organization with an office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705. (**Exhibit 1**.)

10. The CDC is an agency within the Executive Branch of the United States Government, organized within HHS. The CDC is an agency within the meaning of 5 U.S.C.§ 552(f).

11. HHS is an agency within the Executive Branch of the United States Government. HHS is an agency within the meaning of 5 U.S.C. § 552(f).

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

FACTS

A. COVID-19 Vaccines

13. In December 2020, the FDA issued emergency use authorizations for the Pfizer-

BioNTech[9] and Moderna[10] COVID-19 vaccines. In February 2021, the FDA issued an emergency use authorization for the Janssen COVID-19 vaccine.[11] There have been subsequent emergency use authorizations issued for these three vaccines for younger age groups, for boosters, and for "mix and match" administration of the three vaccines. In August 2021, the FDA licensed the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older.[12]

14. Although all three novel COVID-19 vaccines available in the United States were developed at record pace, these products have been mandated for a majority of Americans under the threat of losing their jobs, being separated from the military, being excluded from university, and from participating in civil society.[13] The federal government has, for example, issued mandates for private employees, public employees, and the military.[14] Some cities have gone as far as to require COVID-19 vaccines for entry into restaurants, clubs, gyms, entertainment venues, and indoor events.[15]

15. While mandating this product, the federal government has also given the

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[9] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (last visited May 11, 2022).

[10] https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (last visited May 11, 2022).

[11] https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine (last visited May 11, 2022).

[12] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited May 11, 2022).

[13] https://www.whitehouse.gov/covidplan/ (last visited May 11, 2022).

[14] https://www.whitehouse.gov/covidplan/ (last visited May 11, 2022) https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard (last visited May 11, 2022); https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination (last visited May 11, 2022); https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONA VIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited May 11, 2022).

[15] https://sf.gov/information/vaccine-required (last visited May 11, 2022); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited May 11, 2022).

pharmaceutical companies selling these vaccines, and anyone associated with administering them, complete legal immunity for any injury caused by these vaccines. 42 U.S.C. § 247d-6d (providing that any "manufacturer" of "any vaccine, used to … prevent or mitigate COVID-19" shall be "immune from suit and liability under Federal and State law with respect to all claims … resulting from … [its] use by an individual"). These pharmaceutical companies are even immune from liability for willful misconduct unless the federal government, which promoted and licensed this product, first brings this claim. *Id*.

B. Vaccine Safety Monitoring

16. Because COVID-19 vaccines are being mandated for millions of Americans, it is essential that our federal health agencies ensure that these products are safe and afford the American people transparency regarding the data supporting that claim.

17. The CDC is one of the primary federal agencies responsible for monitoring vaccine safety, including the safety of COVID-19 vaccines. The CDC claims that "COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**[.]"[16]

18. The apparent primary way that the CDC claims to monitor the safety of COVID-19 vaccines is through v-safe app,[17] which "uses text messaging and web surveys to give personalized health check- ins after [one] receives a COVID-19 vaccine."[18] The app allows users to "quickly tell CDC if [they] have any side effects after getting a COVID-19 vaccine[,]" which "helps CDC monitor the safety of COVID-19 vaccines in near real time."

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[16] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (last visited May 11, 2022).

[17] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html (listing v-safe as one of the ways "CDC expanded and strengthened the country's ability to monitory vaccine safety") (last visited May 11, 2022).

[18] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html (last visited May 11, 2022).

19. On May 20, 2021, the CDC published a document titled "V-safe active surveillance for COVID-19 vaccine safety" (the "**V-Safe Protocol**").[19] The document explains that "[t]he purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[20]

20. The V-Safe Protocol indicates that "V-safe data will be collected, managed, and housed on a secure server by Oracle."[21] The V-Safe Protocol further provides:

> Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the secure server.[22]

The V-Safe Protocol further states, "No PII [personally identifiable information] will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests."[23]

21. The CDC's V-Safe Protocol stresses the importance of this data and that it "is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports."[24] Despite these claims, v-safe data is not yet available to the public.

22. To ensure that the CDC acts in furtherance of its commitment to "openness and

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[19] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf (last visited May 11, 2022).

[20] *Id*. at 3.

[21] *Id*. at 8.

[22] *Id*. at 9 (emphasis added).

[23] *Id*. at 10.

[24] *Id*. at 12.

accountability" and to gain access to critical data regarding the safety of COVID-19 vaccines, Plaintiff made a FOIA request to the CDC for information regarding v-safe.

C. The FOIA Request (IR#0738)

23. On April 1, 2022, Plaintiff submitted the FOIA Request to the CDC seeking:

> **All data submitted to v-safe since January 1, 2020.**

(Exhibit 2.)

24. On April 2, 2022, the CDC emailed Plaintiff and assigned its FOIA request Case Number 22-01281-FOIA. (**Exhibit 3**.)

25. On April 6, 2022, the CDC issued an acknowledgment letter to Plaintiff which stated in part:

> **The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated April 1, 2022. Your request assigned number is #22-01281-FOIA, and it has been placed in our complex processing queue (copy enclosed).**

(Exhibit 4.)

26. The acknowledgment letter also detailed that the agency "will require more than thirty working days to respond to [Plaintiff's] request because: We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request." *Id*.

27. Despite the passing of more than thirty days, Plaintiff has received no other communication from CDC regarding this FOIA request.

ARGUMENT

28. HHS and CDC failed to timely respond to Plaintiff's FOIA request. 5 U.S.C. § 552(a)(6)(A)(i).

29. Despite the passing of more than thirty days, to date, CDC has not provided ICAN with a determination of whether it intends to comply with the FOIA Request as required by 5 U.S.C. § 552(a)(6)(A)(i). *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) ("[I]n order to make a 'determination' and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and the reasons for withholding any documents; and (iii) inform the requester that it can appeal whatever portion of the 'determination' is adverse.") When an agency takes more than thirty days to provide a 'determination' an "agency cannot rely on the administrative exhaustion requirement to keep cases from getting into court." *Id*. at 189.

30. For these reasons, CDC has failed to abide by the requirements of FOIA and has forced ICAN to come before this Court to seek an order directing CDC to expeditiously produce all documents responsive to its FOIA request. The information ICAN seeks is simply too important to the current public discourse and safety monitoring regarding the COVID-19 vaccines to allow CDC to withhold such information from the public.

31. It is public knowledge that the data submitted to v-safe exists, therefore, that data should be produced to Plaintiff and the public forthwith.

REQUESTS RELIEF

WHEREFORE, Plaintiff prays that this Court:

a. Provide for expeditious proceedings in this action;

b. Enter an order directing the CDC to produce all v-safe data within one day from the date of any such order;

c. Enter an order directing the CDC to produce all other documents responsive to

each of the FOIA Requests within 10 days from the date of any such order;

d. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

e. Grant such other and further relief as the Court may deem just and proper.

Dated: May 17, 2022

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